Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Quasar MD21 Infrared Heat Lamp.

Company making the submission:

	This summary is submitted in behalf of:	or	This summary is submitted by:
Name:	**Quantum Skincare, Inc.**		Delphi Consulting Group
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Contact:	Jim Cobb President		J. Harvey Knauss Consultant
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1. **Device Name:**

Trade/Proprietary Name:	Quasar MD21 Infrared Heat Lamp.
Common/Usual Name:	Infrared heat lamp.
Classification Name:	Infrared lamp 21 CFR § 890.5500

2. **Predicate Device:**

   The Quasar MD21 Infrared Heat Lamp is substantially equivalent to other infrared lamps on the market, such as the Mu Photonics Pain Therapist, K012598 manufactured by Nu Photonics, Inc., and Biolight PCD,

3. **Intended use of the Device:**

   The Quasar MD21 infrared heat lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature. This device may be used to provide temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm. This device may temporarily increase local blood circulation, and may be used to promote relaxation of the muscle tissue.

4. **Description of the Device:**

   The Quasar MD21 consists of a collection of both infrared and red diodes [LEDs], packaged in a compact plastic head. The system emits pulsed light in the infrared spectrum to provide topical heating. The red diodes [LEDs], provide a visible indication that the unit is in operation. For operation turn on LEDs for a time period of twenty-five (25) minutes prior to use.

5. **Summary of the technological characteristics of the device Compared to predicate devices:**

   The Quasar MD21 and the above referenced predicate devices are infrared lamps as defined in 21 CFR § 890.5500. These devices utilize infrared diodes [LEDs], to provide topical heating for the temporary relied of muscle and/or joint pain. The temperatures achieved by these devices are the same, using a similar number of diodes [LEDs], over a similar coverage area. The devices are handheld, and intended to be placed directly on the skin or held just over the skin to provide the heating.

6. **Testing:**

   Testing of the Quasar MD21 included functional performance testing and electrical safety testing.

7. **Conclusions:**

   Based upon the testing and comparison to the predicate devices, the Quasar MD21 has the same intended uses, with similar technological characteristics. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Quantum Skincare, Inc.
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071-3404

Re: K032379
Trade/Device Name: Quasar MD21, Infrared Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: October 9, 2003
Received: October 14, 2003

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K032379

Device Name: **Quasar MD21, Infrared Lamp**

Indications for use:

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032379